**ALL NEW AND ONGOING RESEARCH PROJECT UPDATES MUST BE SUBMITTED TO** [**RESEARCH@TGH.ORG**](mailto:RESEARCH@TGH.ORG)

Thank you for your interest in performing/conducting your research project/study at Tampa General Hospital (TGH). Please follow the instructions for Research Study submission:

| **Submission Instructions** |
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| **INTRODUCTION:**  TGH has three research study submission options:   * **Option #1 - PRE-SUBMISSION** * **Option #2 - COMPLETE SUBMISSION** * **Option #3 – COMPLETE SUBMISSION FOR RETROSPECTIVE CHART REVIEW STUDIES**   **Option #3 - COMPLETE SUBMISSION FOR RETROSPECTIVE CHART REVIEW STUDIES**   * Any retrospective chart review study with NO informed consent, budget and/or contract allows your study to be submitted under Option #3   **Option #3 Instructions:**   * **STEP 1 (STUDY TEAM):** Obtain all study documents and complete **Section A** of the TGH Research Study Proposal Form. * **STEP 2 (STUDY TEAM):** Complete the entire TGH Research Study Proposal Form **Sections B – D**, including signing and dating the form. * **STEP 3 (STUDY TEAM):** Submit the completed TGH Research Study Proposal Form and study documents to [research@tgh.org](mailto:research@tgh.org).   TGH Office of Cline Research (OCR) will begin reviewing the research project/study once all required study documents are received by the OCR. If you need clarification on the required documents, please contact[research@tgh.org](mailto:research@tgh.org)  **APPROVALS REQUIRED TO START STUDY ACTIVITIES:**  For all studies conducted at TGH using any TGH resources, data (e.g., medical record information) and/or facilities, two written approvals are required prior to starting the study:   1. Institutional Review Board (IRB) approval; and 2. TGH OCR approval   **TGH Clinical Research Website: Study Submissions**  To obtain further Instructions and Forms:  <https://www.tgh.org/more-about-tgh/clinical-research/study-submission-0>  ***Always go to the TGH Clinical Research website to obtain the current information and forms*** |

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| **SECTION A – STUDY DOCUMENTS** |

Select all documents that are included in your submission:

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| **For ALL studies the following documents must be submitted:** |
| Research Study Proposal Form  Study protocol (Version date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_)  IRB Application **for Investigator Initiated studies (IIT)**. If there is no informed consent, the request for a waiver of Consent and Authorization must submitted with the application  Data collection sheet  Current CV, signed and dated for the principal investigator |

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| **B. GENERAL STUDY INFORMATION** |

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| Full Study Title: |  |
| Short Title: (descriptive title to be used for study ID in EPIC/EMR and CTMS) |  |
| Study Protocol Number: |  |
| IRB #: | Pending available |
| Principal Investigator (PI) Name: |  |
| Study Indication: |  |

**Short Study Description:** (1-2 sentences summarizing the purpose of the study, 200 max character limit)

**PI Information**

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| Affiliation and Department: |  |
| Mailing Address: |  |
| Telephone: |  |
| E-mail: |  |
| Pager/Cell Phone: |  |
| Credentialed at TGH? | Yes No Pending |

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| **C. Study Details** |

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| Number of Planned Subjects: |  | | |
| Therapeutic Area of the Study (select only one option – most relevant area): | Allergy, Asthma and Immunology  Anesthesiology  Anthropology  Cardiology and  Cardiothoracic Surgery  College of Medicine  Critical Care and Trauma  Emergency Medicine  Engineering  Gastroenterology and  Digestive Diseases  Genetics and Metabolism  Hepatology  Infectious Disease  Internal Medicine | Infectious Disease  Internal Medicine  Laboratory  Mental Health  Molecular Medicine  Neonatology  Nephrology  Neurology and  Neurosurgery  Nursing  OB/GYN  Oncology  Ophthalmology  Orthopaedics  Otolaryngology | Pastoral Care  Pathology  Pediatrics  Pharmacology  Pharmacy  Plastic Surgery  Poison Center  Public Health  Pulmonology  Radiology  Surgery  Transplant  Trauma Surgery  Urology  Other, specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| IRB Name: | USF IRB  Other, specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | |

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| **D. Study Personnel** |

**Sub-Investigators (Additional Sub-Investigators should be listed in Section D.1.)**

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| Name: |  |
| Telephone: |  |
| E-mail: |  |
| Pager/Cell Phone: |  |

**Primary Study Coordinator (SC):**

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| Name: |  |
| Telephone: |  |
| E-mail: |  |
| Pager/Cell Phone: |  |

**Study Contact: (Any additional study personnel should be listed in Section D.1.)**

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| Name: |  |
| Telephone: |  |
| E-mail: |  |
| Pager/Cell Phone: |  |

**Submitter Signature:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ **Date of Signature:** \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

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| Section D.1. Complete the below information for any additional study personnel | |
| Name: |  |
| E-mail: |  |
| Role: |  |

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